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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,097	11/08/2005	Samuel I. Stupp	NANO 106 US2 (NU 22088)	2444
62249	7590	04/24/2007	EXAMINER	
BENET GROUP LLC C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/534,097	STUPP ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/6/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                 |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application       |
| Paper No(s)/Mail Date <u>5/12/06 &amp; 3/7/07</u> .                                    | 6) <input checked="" type="checkbox"/> Other: <u>Notice to comply</u> . |

## **DETAILED ACTION**

### *Status of the claims*

Claims 1-11 are pending.

### *Continuing data and priority*

This application is a continuation application of 09561226 filed 4/28/2000 (now US Pat. No. 6924264). Applicant's claim for the benefit of a prior-filed application 60425536 filed 11/12/2002 and 60425689 filed 11/12/2002 under 35 U.S.C. 119(e) is acknowledged. Yet, it is of note that 60425536 has no adequate support for the claimed invention of instant claims 4-6 (see below). Thus, this application do not have the benefit of prior filed 60425536 filed 11/12/2002.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

1. Claims 1-3, drawn to a composition for material formation on self-assembled peptide-amphiphiles, are classified in class 530, subclass 350, and class 424, subclass 278.1.
2. Claims 4-8, drawn to a method of making materials on self-assembled peptide amphiphile comprising preparing a first solution that contains ionically charged peptide-amphiphiles and a salt and a second solution comprising an ion from the material wherein the ion has opposite signed ionic charge to the peptide-amphiphiles in said first solution, and mixing the first and second solutions, are classified in class 514, subclass 2.
3. Claims 9-11, drawn to a composition comprising a material, e.g., magnetic material, which is nucleated and grown on the surface of nanofiber comprising the self-assembled peptide amphiphiles.

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The inventions listed as Groups 1-3 do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed heat shock protein is obvious over Wong et al. (*Nano Lett.* (2002, June) 2, 583-587). Wong et al. teach preparation of SiO<sub>2</sub>/Au composite on out-surface of nanoparticles (see Scheme 1, page 585) that contain self-assembled peptide amphiphiles (Lys<sub>200</sub>Cys<sub>30</sub>) by mixing the solution that comprises hydrogen bromide salt of Lys<sub>200</sub>Cys<sub>30</sub> (see Figure 1 legend) with SiO<sub>2</sub> solution. Wong et al. teach the method of instant claim 4-6 (see the 102 rejection in this Office action for the detail). Thus, the claimed method does not constitute a special technical feature as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

*Additional Election Under 35 USC 121*

Applicants are further required under 35 US 121 (1) to elect a single disclosed peptide or a nucleotide sequence encoding the peptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group 3 is elected, applicant is required to elect one type of material from claim 11 because the materials recited in claim 11, e.g., magnetic material, is distinct from cells in structure and function.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 USC 121 since the above-mentioned materials are structurally and functionally (e.g., the magnetic material versus cells), and each material is thus directed to independent invention.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.

During a telephone conversation with Maria L. Maebius on April 5, 2007, a provisional election was made with traverse to prosecute the invention of Group 2, claims 4-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-3 and 7-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b). Claims 4-6 are examined in this Office action.

### ***IDS***

The references cited in the IDS filed 5/12/06 and the IDS filed 3/7/2007 have been considered by Examiner.

### ***Objections to specification***

(1) At [0023], the description to Figure 5 should describe "1", "2A" and "2B" shown in Figure 5 accordingly.

(2) At [0051], line 1, "Molecule1" should be changed to "Molecule 1".

(3) At [0068], "HBTU" should be spelled out in full for the first instance of use. See also [0069], line 6, "DiEA"; and [0070], line 2, "TIS" and "TFA".

### ***Objection to the claims***

Claims 4-6 are objected to because in claim 4, lines 3, 5 and 8, "material" should be changed to "materials" in order for consistence with "materials" recited at line 1.

Claim 5 is objected to because, at line 2, before "material", the article "the" or "said" should be inserted. Also, in claim 5, after "further comprising" should insert colon ":" in order for consistency with the recitation of claims 4 and 6.

### ***Objection to the drawing***

The drawing Figure 4 (filed 5/6/2005) is objected to under 37 CFR 1.83(a) because the right side of this figure appears to be incomplete. Therefore, the clear and complete drawing thereof must be provided. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

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At [0007], line 1, 3, and 5, one peptide sequence (IKVAV) is disclosed without SEQ ID NO identification. Similarly, see also [0026], lines 6 and 8; [0032], line 13; [0036], line 7; [0048], line 2; page 21, line 6; page 22, line 2; page 25, line 13; [0064], line 4; [0065], lines 2 and 4; [0066], line 10; and page 27, line 3.

At [0026], last line, one peptide sequence (YIGSR) is disclosed without SEQ ID NO identification. Similarly, see also [0026] at page 9, line 3; and page 25, line 13.

At [0026], page 9, line 6, one peptide sequence is disclosed without SEQ ID NO identification.

At page 13, Table 1, seventeen peptide sequences are disclosed without SEQ ID NO identification.

At page 15, Table 2, six peptide sequences are disclosed without SEQ ID NO identification.

At page 19, lines 7-8, six peptide sequences are disclosed without SEQ ID NO identification.

At [0062], lines 3 and 6, two peptide sequences are disclosed without SEQ ID NO identification.

The above-discussed sequences are subjected to the attached “**sequence Comply**”.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821 (e) or 1.821(f)



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or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites “first solution ...one salt providing one ion from the material” (line 3), and “second solution with an ion from the material”. The claim does not make it clear whether or not the solution actually contains the material, e.g., the “salt” can be separated from said material and put into said solution without physically addition of the material per se.

Also, claim 4 is unclear in “one ionically charged species of peptide amphiphile” (lines 2-3) because the claim does not make it clear (i) whether or not the peptide amphiphile (in the first solution) is not homogenous, i.e., some peptide amphiphiles have ionic charge while the other do not, and (ii) whether or not said “ionically charged species” refers to net negatively or positively charged molecule, or zwitterions.

Further, claim 4 recites “form said material substantially on said nanofiber surface”; the metes and bounds of the phrase “substantially on” is not apparent because it ambiguously refers to the material loosely bound to said surface, or bound firmly but with various extents. The

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specification do not define it in this regard. The claims 5-8 which depend from claim 4 are also rejected.

***Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Wong et al.

(*Nano Lett.* (2002, June) 2, 583-587).

Wong et al. teach preparation of SiO<sub>2</sub>/Au composite on out-surface of nanoparticles (see Scheme 1, page 585) that contain self-assembled peptide amphiphiles (Lys<sub>200</sub>Cys<sub>30</sub>) by mixing the solution (A) that comprises hydrogen bromide salt of Lys<sub>200</sub>Cys<sub>30</sub> (see Figure 1 legend) with SiO<sub>2</sub> solution (B). Solution (A) also called “Au solution” (see line 4 of Figure 1 legend) further comprises Au salts which is prepared by citrate reduction taught by the incorporated reference 32 (see “*Discussion of art*”), i.e., Au<sup>3+</sup> has the same signed ionic charge as positively charged Lys ε-amine group in aqueous solution. Here, the SiO<sub>2</sub>/Au composite are equivalent to instant “material” to be formed; solution A is equivalent to instant first solution and solution B to instant *second* solution. In solution B, the SiO<sub>2</sub> (colloidal particles of SiO<sub>2</sub> are negatively charged, due to O<sup>-</sup> or O<sup>-2</sup>, see “*Discussion of art*”), i.e., solution B contains ions having opposite signed charge to Au<sup>3+</sup>/Lys<sub>200</sub>Cys<sub>30</sub>. The above teachings meet all the limitations of claim 4. Therefore, Wong et al. teach the method of claim 4.

Wong et al teach that formation of  $\text{Au}^{3+}/\text{Lys}_{200}\text{Cys}_{30}$  nanofibers and  $\text{SiO}_2/\text{Lys}_{200}\text{Cys}_{30}$  nanofibers is time-dependent, e.g., the formation of  $\text{SiO}_2/\text{Au}^{3+}/\text{Lys}_{200}\text{Cys}_{30}$  nanoparticles emerges after reaction of the solution A with solution B (see Figure 1 legend, lines 7-8). Since the reaction time is inherently relative to controlling size and growth of the materials ( $\text{SiO}_2/\text{Au}$ ) on the amphiphilic peptides, the above Wong's teachings anticipate claims 5.

Wong et al. teach pH-dependent charge state for lysine  $\epsilon$ -amino groups and  $\text{SiO}_2$  (see left column, 2<sup>nd</sup> paragraph, lines 16-22, page 584) and teach that the pH of the solution mixture is 4 (right column, lines 1-2), suggesting a requirement of adjusting pH, which anticipates claim 6.

- Claims 4-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Slocik et al. (*Nano Lett.* (2002, March) 2, 169-173).

In abstract and left column, page 170, Slocik et al. teach preparation of nanomaterial that contains histidine-rich self-assemble amphiphilic peptides (HREs) and the "material", e.g., metal sulfide composite, wherein HREs stabilize nanoclusters (see left column, last paragraph, lines 7-9, page 172). At page 173, left column, lines 18-25, Slocik et al. teach addition of the solution of  $\text{AgNO}_3$  to an aqueous solution of peptide followed by dilution with Tris buffer, 0.10 M, pH 8.6 under which condition His-side chains possess positive charges and thus have the same signed charges as  $\text{Ag}^+$  ions. Such the resultant solution (i.e., solution (A) is equivalent to instant *first* solution. Slocik et al. further teach addition of an aqueous solution of  $\text{Na}_2\text{S}$  (i.e., solution (B), equivalent to instant *second* solution) to solution (A) to produce  $\text{Ag}_2\text{S}/\text{HREs}$  nanofibers. The Slocik et al. teachings anticipate claim 4.

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In the above preparation process, the dilution with Tris buffer, pH 8.6, is comparable to adjusting pH of the solution thereof, as applied to claim 6.

Slocik et al. teach incubation of  $\text{AgNO}_3$  solution with the peptide solution for certain period time, e.g., 15 min, and reaction time for incubating solutions A and B is 4 hour (see left column, page 173), because said reaction time is inherently relative to controlling size and growth of the material (metal sulfate,  $\text{Ag}_2\text{S}$ ) on the amphiphilic peptides, the above Slocik et al. teachings anticipate claims 5.

### ***Conclusion***

No claims are allowed.

### ***Discussion of art***

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

- Shih et al. (Langmuri (2002) 18, 3332-3335) teach preparation of gold nanoparticle by reaction of  $\text{HauCl}_4$  with sodium citrate (see Scheme 1, page 3333). This reference refers to reference 32 cited in line 4 of Figure 2 legend of Wong et al.
- Jin et al. (*Phys. Rev. Lett.* (2001) 86, 1793-1796) teach that the negatively charged oxygen ions, e.g.,  $\text{O}^-$  or  $\text{O}^{2-}$  in  $\text{SiO}_2$  (see abstract).

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

*swl*

Samuel Wei Liu, Ph.D.  
Art Unit 1656, Examiner  
April 9, 2007

*Kathleen Kerr Bragdon*  
KATHLEEN KERR BRAGDON, PH.D.  
SUPERVISORY PATENT EXAMINER